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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,502	12/19/2001	Heiner Glombik	02481.1771	8511

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EXAMINER	
KRISHNAN, GANAPATHY	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,502	GLOMBIK ET AL.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8,9,11,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-5,9,11,13 and 14* is/are allowed.

6)☒ Claim(s) *8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 1/31/2005 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 6, 7, 10, 12 and 15-17 have been canceled.

2. Claim 8 has been amended.

Claims 1-5, 8, 9, 11, 13 and 14 are pending in the case. Withdrawn claims 9, 11, 13 and 14 have been rejoined since the compounds of claim 1 are found allowable.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

The following new objection and rejection are made of record.

Specification

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The attempt to incorporate subject matter into this application by reference to WO 98/08871, WO 9903861, WO 97/41097 for the following active compounds: antidiabetics, GLP-1 derivatives, hypoglycemic compounds, sulfonyl ureas, biguanides, meglitinides, oxadiazolidinediones, thiazolidinediones, glucosidase inhibitors, glucagons antagonists, GLP-1

antagonists, potassium channel openers is improper because the active compounds for the pharmaceutical combination with compounds of formula I of the instant invention are seen to be essential to the instant invention.

The disclosure is objected to because of the following informalities: The incorporation of subject matter into this application by reference to WO 98/08871, WO 9903861, WO 97/41097 for the following active compounds: antidiabetics, GLP-1 derivatives, hypoglycemic compounds, sulfonyl ureas, biguanides, meglitinides, oxadiazolidinediones, thiazolidinediones, glucosidase inhibitors, glucagons antagonists, GLP-1 antagonists, potassium channel openers is objected to as being improper.

Appropriate correction is required.

Claim Objections

Claim 8 is objected to because of the following informalities: Claim 8 recites several Markush members but does not recite the proper Markush language "selected from the group consisting of". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the pharmaceutical combination comprising one or more compounds of claim 1 and 3-hydroxy-3-methylglutaryl Coenzyme A, cholesterol absorption inhibitors and insulin does not provide enablement for all of the other compounds or class of compounds recited in claim 8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims
(B) The state of the prior art
© The level of one of ordinary skill
(D) The level of predictability in the art
(E) The amount of direction provided by the inventor
(F) The existence of working examples
(G) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claim 8 is drawn to a pharmaceutical composition comprising one or more compounds of claim 1 and one further compound chosen from a group that includes several genera of compounds.

The state of the prior art

The examiner notes that prior art Vaccaro et al (US 5656624) teach combinations of cholesterol absorption inhibitors and HMGCoA reductase inhibitors (col. 5, lines 10-30 and col. 8, lines 21-34). Insulin is a well-known antidiabetic. However the prior art is silent regarding the combination of all of the other classes of compounds that are recited in claim 8 using functional language.

The level of predictability in the art

The examiner acknowledges the probability that the instantly claimed compounds of formula (I) as recited in claim 1 may be combined with other classes of compounds. However, applicant functionally describes compounds, which may have divergent chemical cores and structures. The skilled artisan could not predict the ratios of components for such "combinations" and there is no guidance or predictive correlation provided by applicant or pointed out in the prior art. There is not seen sufficient data in the prior art or in the instant disclosure to assert that active agent which fall under the definition of the general classes of compounds that are recited using functional language can be combined since such combinations require consideration of potential problems with regarding to solubility, compatibility, etc. The art is highly unpredictable regarding such combinations.

The amount of direction provided by the inventor

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to make and use pharmaceutical combinations as instantly claimed. The specification also fails to direct the skilled artisan in correlative prior art procedures which might provide the basis for the same.

The existence of working examples

There are no working examples provided in the specification for making and using combinations of one or more compounds of claim 1 with representative examples of compounds belonging to non-diabetic related classes as recited in claim 8. The examples provided in the specification are drawn to the syntheses of compounds of claim 1 and their effect on cholesterol absorption. The disclosure is silent with regard to ratios, solubility and complexation limitations the skilled artisan would face formulating pharmaceutical compositions as instantly claimed.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the preparation of a pharmaceutical combination of one or more compounds of claim 1 and all of the other classes of compounds recited by functional language except for the pharmaceutical combination comprising one or more compounds of claim 1 and 3-hydroxy-3-methylglutaryl Coenzyme A, cholesterol absorption inhibitors and insulin. One of ordinary skill in the art would have to carry out the process in order to determine the compatibility, the solubility and amount etc. for making such a combination.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites insulins as one of the Markush members. It is not clear if this plural recitation includes compounds other than the regular insulin. Clarification is needed.

Conclusion

1. Claims 1-5 and 9, 11, 13 and 14 drawn to compounds of formula (I) comprising specific substitution patterns, their pharmaceutical composition comprising a pharmaceutically acceptable carrier and the method of treating impaired lipid metabolism, hyperlipidemia, lowering or maintaining cholesterol level and treating insulin resistance are neither taught or fairly suggested by the prior art of record.
2. Claim 8 is rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached between 8.30am-5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

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SUPERVISORY PATENT EXAMINER
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